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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,101	07/08/2003	Ying Luo	RIGL-010CIP3	5361

24353 7590 01/05/2007  
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EXAMINER
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RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/616,101

Applicant(s)

LUO ET AL.

Examiner

Manjunath Rao

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-47 is/are pending in the application.
- 4a) Of the above claim(s) 45-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☒ Other: Sequence alignments.

### **DETAILED ACTION**

Claims 38-47 are currently pending and are present for examination. Claims 38-44 are now under consideration. Claims 45-47 remain withdrawn from consideration being drawn to non-elected invention.

Applicants' amendments and arguments filed on 8-28-06, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. Examiner acknowledges the amendment to 1<sup>st</sup> line of the specification as well as provision of sequence identifiers for those sequences recited in the specification.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

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reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 38-40, 42 are rejected under 35 U.S.C. 102(e) as being anticipated by any or all of the following references;

Christenson et al. (US 20030190739A1, effective filing date 6-29-1999),

Daly et al. (US 20020037582A1, with effective filing date 9-23-1998),

Geron Corp (US 6599728, effective filing date 4-13-1999) or

Berthelsen et al. (US 6455290, effective filing date 7-9-1999).

This rejection is based upon the public availability of patents granted to another or printed publications. Claims 38-40, 42 of the instant application are drawn to a composition comprising a recombinant Tankyrase H, a source ADP-ribose wherein said enzyme has ADP-ribose polymerase activity, wherein said composition comprises a test agent, a candidate bioactive agent such as a organic molecule of less than 2500 Da and wherein said polypeptide has an amino acid sequence that is at least 95% identical to SEQ ID NO:3 or 4. All the above reference disclose such a composition comprising a recombinant Tankyrase H, a source ADP-ribose wherein said enzyme has ADP-ribose polymerase activity, wherein said composition comprises a polypeptide having more than 95% sequence identity with either SEQ ID NO:3 or 4 (see enclosed sequence alignments). Thus above references anticipate claims 38-40, 42 of this application as written.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the reference as applied to claims 38-40, 42 above, and further in view of Smith et al. (Science, Vol. 282, pages 1484-1486, 1998) and the common knowledge in the art regarding mammalian cellular assay and making fusion proteins. Claims 41, 43-44 are drawn to a composition comprising a recombinant Tankyrase H, a source ADP-ribose wherein said enzyme has ADP-ribose polymerase activity, wherein said composition comprises a test agent such as a peptide and wherein said composition is a mammalian cellular composition and the tankyrase H is a fusion protein.

The anticipation of claims 38-40 and 42 by the above references have already been discussed above. However, not all of them teach a test agent which is a peptide or a composition comprising a mammalian cell encoding a recombinant tankyrase H protein or that the tankyrase H protein is a fusion protein.

Smith et al. teach that tankyrase is a Poly (ADP-ribose) polymerase found at human telomeres and that it binds to TRF1 a negative regulator of telomere length. The reference also teaches a method of making histidine tagged tankyrase fusion protein and transfection of the same to insect cells.

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With the teachings of the above references in hand, it would have been obvious to one of ordinary skill in the art to arrive at a mammalian cell composition expressing the recombinant tankyrase as a His-tagged fusion protein. One of ordinary skill in the art would have been motivated to do so in view the teaching of Smith et al. that tankyrase regulates the telomere length in mammalian cells. Therefore one of ordinary skill in the art would make the vector expressing the recombinant fusion protein as taught by Smith and express the same in a mammalian cell such as a HeLa cell in order to study the specific role of tankyrase in cell growth. On similar lines, one of ordinary skill in the art would have been motivated to use random peptides as test agents because it is well known in the art that peptides can bind to enzymes and regulate its activity. One of ordinary skill in the art would have a reasonable expectation of success because Smith et al. teach that tankyrase is a protein that is normally expressed in the mammalian protein and also demonstrate the making of fusion protein that can be expressed in an insect cell which technique could be applied to any mammalian cell.

Therefore the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

***Conclusion***

None of the claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

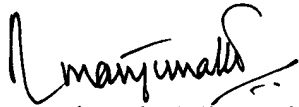
Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Manjunath N. Rao, Ph.D. whose telephone number is 571-272-0939. The Examiner can normally be reached on 7.00 a.m. to 3.30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of

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this application or proceeding should be directed to the receptionist whose telephone number is  
571-272-1600.

A handwritten signature in black ink, appearing to read "Manjunath N. Rao". The signature is stylized with a large initial "M" and a long horizontal stroke extending to the right.

Manjunath N. Rao, Ph.D.

Primary Examiner

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December 23, 2006